REMARKS

The Examiner has rejected claims 1-6, 11, and 14 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,993,844 (the '844 patent). The Examiner indicates that the '844 patent anticipates claims 1-6, 11, and 14 because the '844 patent describes graft constructs that are endotoxin-free and, according to the Examiner, a graft construct that is "endotoxin-free" is within the ranges claimed in the present application. Applicants respectfully traverse the Examiner's rejection. Claims 1-6, 11, and 14 are not anticipated by the '844 patent.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). The '844 patent describes a graft prosthesis from which non-collagenous material has been removed (see column 4, lines 1-3 of the '844 patent). The graft construct described in the '844 patent is rendered substantially free of glycoproteins, glycosaminoglycans, proteoglycans, and non-collagenous proteins (see column 3, lines 41-44). The graft constructs claimed in claims 1-6, 11, and 14 of the present application comprise a "collagen-based matrix structure." As stated on page 14, lines 1-2 of the present application, the matrices in accordance with the present invention contain one or more naturally occurring components including glycoproteins, glycosaminoglycans, and proteoglycans and/or growth factors. The '844 patent describes graft prostheses from which these components have been removed. Thus, the '844 patent cannot anticipate claims 1-6, 11, and 14. Withdrawal of the rejection of claims 1-6, 11, and 14 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent is respectfully requested.

Moreover, the Examiner contends that U.S. Provisional Application Serial No. 60/024,542 does not contain support for the phrase "endotoxin units per gram" in claim 3 because, although the '542 application recites less than 5 "EU/g," the '542 application does not set forth the meaning of "EU/g" and, according to the Examiner, this phrase cannot be assumed to mean "endotoxin units per gram." Contrary to the Examiner's contention, it was well-known before the priority date of the present application that "EU/g" means "endotoxin units per gram."

Applicants transmit herewith Exhibits A-J, all published before the priority date of the present application. Exhibit B, for example, is titled "Guide for the Use of the International System of Units (SI)." On page 34 of Exhibit B, the document shows that it was well-known before the priority date of the present application that "g" means "gram" (see bracketed text on page 34). Exhibits C (page 2), D, E, F, G (page 1), H (pages 1 and 4), I (page 2), and J (page 13) (see bracketed text in all documents) show that it was well-known before the priority date of the present application that "EU" means "endotoxin units." Each of these references defines "EU" as meaning "endotoxin units." Exhibit J shows the usage of "EU/g" on page 14 of the document, Exhibit C (page 4) shows the usage of "EU/kg," and pages 32-33 of Exhibit A show the usage of "EU/g" and state that "EU/g" means "endotoxin units per gram."

Accordingly, it was well-known in the art before the priority date of the present application that "g" means "gram" and that "EU" means "endotoxin units." Thus, the '542 application provides support for the phrase "less than 5 endotoxin units per gram" in claim 3 when the application recites "5 EU/g." Therefore, the '844 patent is not proper prior art to claim 3. Applicants further request withdrawal of the rejection of claim 3 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent because the '844 patent is not proper prior art to claim 3.

The Examiner has rejected claims 7-10 and 16-20 under 35 U.S.C. § 102(e) as allegedly being anticipated by the '844 patent or, in the alternative, as being obvious under 35 U.S.C. § 103(a) over the '844 patent. The arguments discussed above, in the first two paragraphs of this section of the response, apply with equal force to this rejection. Moreover, the subject matter of claims 9, 10, and 16-20 is not disclosed or suggested by the '844 patent. The '844 patent provides no suggestion of cleaning the graft prosthesis prior to delamination (see claims 9, 10, and 16-20). Withdrawal of the rejection of claims 7-10 and 16-20 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent, or under 35 U.S.C. § 103(a) as being obvious over the '844 patent is respectfully requested, based on both of the foregoing arguments.

The Examiner has rejected claims 12 and 13 under 35 U.S.C. § 103(a) as being obvious over the '844 patent. The Examiner has also rejected claim 15 under 35 U.S.C. § 103(a)

as being obvious over the '844 patent in combination with Braun. The arguments discussed above, in the first two paragraphs of this section of the response, apply with equal force to this rejection in the context of obviousness. Withdrawal of the rejection of claims 12 and 13 under 35 U.S.C. § 103(a) as being obvious over the '844 patent is respectfully requested. Withdrawal of the rejection of claim 15 under 35 U.S.C. § 103(a) as being obvious over the '844 patent in combination with Braun is respectfully requested.

The Examiner also pointed in the office action to Rule 41.202, in particular sections (a)(4) and (d), covering the requirement to make a showing of priority. The present application claims the ***same priority date*** as the patent or published application claiming interfering subject matter so it is Applicants' understanding that a priority showing under Rule 41.202(a)(4) and (d) is not required for the present application.

Applicants seek to provoke an interference with U.S. Patent No. 6,206,931, and one of the issues to be decided in the interference will be *determination of the correct inventive entity for the inventions that are now claimed in the above-captioned application and in U.S. Patent No. 6,206,931.* In *Sewall v. Walters*, the Federal Circuit stated that "[i]n this case, Sewall admits that he did not independently conceive the subject matter recited in the count. Instead, Sewall contends that he aided Walters in the conception of that subject matter, and therefore, that he is a joint inventor and should be designated as such pursuant to 35 U.S.C. § 116. This case therefore comes to us in the context of an originality contest as opposed to a priority contest. *Applegate v. Scherer*, 332 F.2d 571, 573 n. 1, 141 USPQ 796, 798 n. 1 (CCPA 1964) ("[I]n an originality case the issue is not who is the first or prior inventor, but who made the invention."). The "inventorship" issue to be decided is thus merely who conceived the invention for which patent protection is sought, and not who first conceived that invention." *See Sewall v. Walters*, 21 F.3d at 415, 30 USPQ2d at 1358 (Fed. Cir. 1994).

Sewall v. Walters was an interference case decided by the Board of Patent Appeals and Interferences, and the Board's decision was reviewed by the Federal Circuit. The Federal Circuit in *Sewall v. Walters* concluded that an interference proceeding can be an originality

contest. The interference that Applicants are attempting to provoke will be at least, in part, an originality case and the issue of originality (*i.e.*, proper inventorship) will be decided. Because the present application claims the ***same priority date*** as the '931 patent it is Applicants' understanding that a priority showing under Rule 41.202(a)(4) and (d) is not required for the present application. Applicants' spoke on the phone with Examiner Prebilic about this issue and he said to make this point in the present response to office action in reply to his discussion of Rule 41.202 in his June 7, 2006 office action.

CONCLUSION

The foregoing remarks are believed to fully respond to the Examiner's rejections. Applicants respectfully request issuance of an action indicating that the claims are allowable, and issuance of a declaration of interference.

Respectfully submitted,

Rebecca Ball

Rebecca L. Ball
Registration No. 46,535
Attorney for Applicants

RVB/wlb
Indianapolis, Indiana 46204
854214v1 INDS02